October 2, 2003

Steven J. Barbee, Ph.D.
Director, Environmental Hygiene and Toxicology
Arch Chemicals, Inc..
501 Merritt 7, P.O. Box 5204
Norwalk, CT 06856-5204

Dear Dr. Barbee:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Hydroquinone bis(2-hydroxyethyl) ether posted on the ChemRTK HPV Challenge Program Web site on June 3, 2003. I commend Arch Chemicals, Inc. for their commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed Comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Arch Chemicals advise the Agency, within 60 days of this posting on the Web site, of any modifications to their submission. Please send any electronic revisions or comments to the following addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Hydroquinone Bis(2-hydroxyethyl) Ether

Summary of EPA Comments

The sponsor, Arch Chemicals, Inc., submitted a test plan and robust summaries to EPA for hydroquinone bis(2-hydroxyethyl) ether (HQEE, CAS No.104-38-1) dated May 2, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on June 3, 2003. In addition, some information was submitted for the proposed analog hydroquinone monomethyl ether (HQMME, CAS No. 150-76-5).

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. The submitter needs to provide measured values for melting point, vapor pressure, and water solubility.

2. Environmental fate. The submitter needs to provide measured ready biodegradation data for this chemical. The submitter also needs to recalculate its fugacity model using measured input values.

3. Health Effects. (a) Adequate data are available for the acute toxicity and repeated-dose toxicity endpoints. (b) Additional data are needed to address genetic (gene mutation and chromosomal aberrations), reproductive, and developmental toxicity because HQMME is not an appropriate analog for HQEE.

4. Ecological Effects. The submitted data for fish and invertebrates are adequate. The algal endpoint either needs to be measured or accompanied by measured analog data to support the predicted value from ECOSAR.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Hydroquinone bis(2-hydroxyethyl) ether Challenge Submission

Test Plan

Physicochemical properties (melting point, boiling point, vapor pressure, partition coefficient, and water solubility

The data provided by the submitter for boiling point and octanol/water partition coefficient are adequate for the purposes of the HPV Challenge Program.

Melting point. The submitter provided an estimated value for this endpoint. EPA prefers that measured physicochemical property data be provided, both to characterize a substance and to provide inputs to transport-distribution models. Thus, the submitter needs to provide measured data. Data from published literature sources are adequate as long as the source is identified. EPA located published data for this endpoint (Beilstein 2003: BEILSTEIN CDS MDL electronic database).

Vapor pressure. The submitter provided an estimated value of 6.63×10^{-7} mm Hg. Estimated values are adequate only if they are below 1×10^{-5} Pa (7.5×10^{-8} mm Hg). The submitter needs to provide measured vapor pressure data for this endpoint following OECD guidelines.

Water solubility. The test plan provided an estimated value. The submitter needs to provide measured data. EPA located published data for this endpoint (Beilstein 2003: BEILSTEIN CDS MDL electronic database).

Environmental fate (photodegradation, stability in water, biodegradation, fugacity

The data provided by the submitter for photodegradation and stability in water are adequate for the purposes of the HPV Challenge Program.

Biodegradation. The submitter provided data following OECD guideline 302B for inherent biodegradation, and concludes in its robust summary that "the test material undergoes rapid biodegradation and would not be expected to be persistent in the environment". However, it is not correct to conclude from the positive results of an inherent test that a chemical would not persist in the environment. Inherent tests, by design, facilitate biodegradation by adaptation of the inoculum. The submitter needs to provide measured ready biodegradation data following OECD Guideline 301.

Fugacity. The submitter needs to re-estimate transport and distribution using measured physicochemical values. The use of default or estimated values provides inaccuracies, which in turn, are enhanced in modeling applications.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Adequate data were submitted for HQEE to address acute toxicity and repeated-dose toxicity endpoints. The submitter's plan to use data for HQMME to satisfy the remaining endpoints for HQEE is not adequate because HQMME is not an appropriate analog (see below). Additional tests, preferably by the oral route of administration, are needed to address the genetic (gene mutation and chromosomal aberrations), reproductive and developmental toxicity of HQEE.

Proposed Analog. EPA believes that HQMME is not an appropriate analog for HQEE. Significant structural differences include the aromatic hydroxyl group in HQMME and the hydroxyethyl groups in HQEE. These differences are reflected in their uses, HQMME being a polymerization inhibitor while HQEE is a polymerization chain extender. EPA agrees that the two substances are expected to follow different metabolic pathways. Thus, HQMME will not be a good predictor of HQEE toxicity.

Ecological Effects (fish, invertebrates, and algae)

The data for the fish and invertebrate endpoints are adequate.

Algae. The only value provided in the test plan was an ECOSAR estimate. Testing is needed to determine the acute toxicity of HQEE to algae unless measured data for an acceptable analog can be supplied to support the predicted ECOSAR value.

Specific Comments on the Robust Summaries

Environmental Fate

Fugacity. The submitter needs to provide in the robust summary the input values used in the fugacity model.

Health Effects. Information describing the purity of the test material is often incomplete.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.